IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **Ethicon Wave 1 cases listed in Exhibit A**	

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE THE GENERAL OPINIONS OF DEFENSE EXPERT CHRISTOPHER RAMSEY, M.D.

Plaintiffs respectfully request that this Court exclude the opinions of Christopher Ramsey, M.D., because he is not qualified as an expert under Federal Rule of Evidence 702, and because he did not engage in a reliable methodology to reach his opinions, as required by the *Daubert* standard.

Dr. Ramsey is a urologist who estimates that 70% of his surgical practice involves treating men. Thus, the majority of his practice is wholly irrelevant to the issues in this litigation, involving the safety and efficacy of Ethicon's pelvic mesh products. Dr. Ramsey has been designated to opine on several TVT products, but his specialty was the TVT-Secur—a device that has been pulled from the market. As noted below, Dr. Ramsey opines that the TVT-Secur is the safest of the TVT products.

In addition to having little relevant experience, Dr. Ramsey lacks the credentials of an expert. He admitted that nothing in his CV bears on any issues regarding transvaginal mesh or the treatment of stress urinary incontinence ("SUI"). Dr. Ramsey's report offers opinions about

the Instructions for Use ("IFU") in the TVT products, but remarkably, he did not know whether the IFU had ever been updated for the TVT or the TVT-O products. Both have been updated several times, and as recently as 2015. For these and other reasons discussed below, Dr. Ramsey is simply not qualified as an expert.

In addition, Dr. Ramsey did not engage in a reliable methodology. His report cites to literature, but his deposition revealed that Ethicon largely chose the literature for him, and helped to draft his reliance list. Dr. Ramsey claims that he requested additional articles, but he could not name one. He also showed an alarming lack of knowledge about information challenging the safety of the TVT-Secur. He did not know that the FDA had expressed concern about the safety of the device; he was unaware of concerns expressed by Ethicon personnel; and he had no knowledge of articles criticizing TVT-Secur in the scientific literature.

Dr. Ramsey's opinions are based on one thing—his clinical experience, during that small portion of his practice in which he treats women. There is no scientific foundation for his opinions, and this Court should exclude him entirely from testifying in the Ethicon Wave 1 cases.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues

in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

ARGUMENT

Dr. Ramsey's opinions should be excluded because he is not qualified under Rule 702 to give opinions about the safety and efficacy of the TVT products discussed in his reports, or about the products' IFU, and because his limited methodology—partially reviewing articles supplied by Ethicon—is not reliable under the *Daubert* standard.

I. Dr. Ramsey is a urologist who primarily operates on men, who has not published anything on any topic relevant to this case, and whose CV reveals no education, experience or other qualifications that relate to the treatment of SUI in any way. Therefore, he is not qualified as an expert under Rule 702.

The first basis for excluding Dr. Ramsey is that he is not qualified to give opinions regarding the TVT line of products. He cannot offer any "scientific, technical, or other specialized knowledge" that would be helpful to the jury. *See* Fed. R. Evid. 702.

A. Dr. Ramsey is a urologist who operates primarily on men, and who has no specialized skills or training that are related to the issues in this case.

Dr. Ramsey is a urologist. He is not a urogynecologist,[1] which is an important distinction in litigation that deals exclusively with products used on women. Dr. Ramsey estimates that **70%** of his surgical practice is spent on treating **men**.[2] He holds himself out as an expert on using the da Vinci robot surgical device, but while that device is sometimes used in surgery on

[1] Ramsey Deposition, April 6-7, 2016, portions attached as Exhibit B, at 149:23-24.
[2] *Id.* at 19:24-20:5.

women, it is never used in surgery to treat stress urinary incontinence.[3] Thus, his primary area of expertise is irrelevant to this litigation.

Dr. Ramsey's curriculum vitae ("CV") is notable for its lack of experience that relates to the treatment of stress urinary incontinence. When counsel pulled out his two-page CV, Dr. Ramsey sarcastically noted that it was "impressive," before acknowledging that "[i]t's not as long as the other ones I've seen."[4] In addition, the information listed therein has little relevance to the issues in this litigation.

> Q. Under "Honors," "Leadership," Publications," "Presentations," and/or "Research," none of the listings in your CVA [verbatim] relate to SUI or transvaginal mesh, correct?
>
> A. In my CV? No. Correct.[5]

Dr. Ramsey does not list any research projects since 1996, and when asked when he had done any research in the last 20 years, he replied: "Not what I would call clinical research."[6] Dr. Ramsey has not conducted any studies treating pelvic pain or dyspareunia.[7] He has not conducted any studies on SUI, or on the treatment of SUI in women.[8] He has not conducted any studies on mesh materials used in Ethicon's products.[9] None of the views that Dr. Ramsey is expressing in his expert reports have ever been published in peer reviewed literature, and he has never submitted an article for that purpose.[10] He has never published an article related to product warnings, and he has never studied the industry standards for warnings.[11]

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[3] *Id.* at 20:6-24.
[4] *Id.* at 146:5-13.
[5] *Id.* at 151:21-152:1. *See also* Ramsey CV, attached as Exhibit C.
[6] *Id.* at 148:22-149:5.
[7] *Id.* at 106:12-107:1.
[8] *Id.* at 106:2-5.
[9] *Id.* at 108:3-5.
[10] *Id.* at 110:17-24.
[11] *Id.* at 111:12-112:8.

Although Dr. Ramsey served as a consultant for Ethicon from 2003-2012,[12] Ethicon never asked him for input in drafting the IFU for any product, never asked him for input on design, and never asked him to perform a risk-benefit analysis as to any product.[13] Ethicon also never approached him to work on any of its committees.[14] In fact, despite his long-term relationship with Ethicon, Dr. Ramsey was unable to name an Ethicon medical director.[15]

As noted, treating SUI is not his surgical specialty. Dr. Ramsey testified that other physicians never refer mesh patients with complications to him, and that when his patients have complications, he refers them to Vanderbilt University.[16] Dr. Ramsey did not attempt to take the FPRM exam, which could have bolstered his credentials as a pelvic surgeon. He did not sit for the exam because he "didn't do most of the things that they [other surgeons] do, which is a lot of pelvic floor." He further acknowledged that had he tried to take the test, he might not have qualified to sit for it, if there had been a minimum requirement for the number of pelvic floor surgeries performed.[17]

As of the time of his deposition, Dr. Ramsey's own website did not list pelvic floor surgery as a specialty.[18] The website for a hospital where Dr. Ramsey does many of his surgeries lists robotic surgery as his special concentration, but does not list treatment of female SUI as one of his concentrations.[19]

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[12] *Id.* at 181:8-10.
[13] *Id.* at 16:3-17.
[14] *Id.* at 14:19-15:6.
[15] *Id.* at 52:12-14.
[16] *Id.* at 72:1-4, 76:18-22.
[17] *Id.* at 150:3-151:9.
[18] *Id.* at 328:11-23. Dr. Ramsey also stated that the website had changed and needed to be updated. (*Id.* at 326:18-327:7).
[19] *Id.* at 329:3-15.

B. Dr. Ramsey showed that he does not have the knowledge that an expert in the field would have when discussing the IFU for the TVT products. For instance, he had no idea that they had been updated several times since the TVT product was launched.

Dr. Ramsey also showed his lack of expertise by testifying that he was not aware of any changes to the Instructions for Use ("IFU") for the TVT-Retropubic or the TVT-O products, from launch until the present.[20] It is remarkable that he would be unaware of any such changes, given that a chart produced by Ethicon shows seven iterations of the TVT-O IFU, and eight iterations of the TVT IFU—both of which were updated in 2015.[21] Notably, the 2015 revisions have added many of the warnings that Plaintiffs in this litigation have stated were needed, including the risks of chronic pain and multiple revision surgeries.[22] Not only was Dr. Ramsey unaware of these changes, he has a false conception of whether they would be required. He testified device manufacturers are not required to warn of all risks in the IFU.[23] Rather, he says that manufacturers only must warn of risks that are unique to the device.[24]

Yet, Dr. Ramsey acknowledged that no medical device manufacturer adheres to the standard that he claims to be applied by the FDA.

> Q. Okay. As you sit here today, can you point to a single medical device IFU that you've used in all your time as a urologist that adheres to your standard of only risk – only listing the risk that is … uniquely associated with that device?
>
> A. None of them do.
>
> Q. None of them do?
>
> A. No.
>
> Q. Not a single medical device IFU that you've ever looked at in your time as a urologist adheres to the standard that you've presented today, correct?

[20] Ramsey Dep., Ex. B, at 121:20-122:9.
[21] Ethicon IFU chart for pelvic mesh products, attached as Exhibit D.
[22] *See* Annotated Updated IFU for TVT, attached as Exhibit E.
[23] Ramsey Dep., Ex. B, at 114:5-8.
[24] *Id.* at 114:9-12.

A. Correct.[25]

Dr. Ramsey also testified that medical device manufacturers should not report on the duration, frequency, or severity of complications in the IFU.[26] Yet, this testimony is directly contradicted by the prior testimony of Ethicon's worldwide medical director, Piet Hinoul, in discussing a study conducted by Ethicon:

> Q. Highlighting the issue that that you can't assume that doctors out there in the communities know of the severity and the duration of these chronic debilitating complications, correct?
>
> A. That's what that states.
>
> Q. And because of that, it is incredibly important for your company, especially because you're dealing with an implant that will -- will be in the woman's body forever potentially, that's why it's so important for you as a manufacturer to do the right thing and make sure when you know of the risks, the chronicness of them, the duration, the severity, you should warn of them, correct?
>
> A. Correct.[27]

Dr. Ramsey fares no better when the discussion turns from FDA standards to industry standards, as it relates to the IFU.

> Q. You don't know what industry standards govern medical device IFUs, correct?
>
> A. I think I would say I know … what standards govern it. The FDA has –
>
> Q. Industry standards.
>
> A. I guess –
>
> Q. Industry standards … -- the standards among the industry. Putting aside regulation standards, are you familiar with the industry standards that govern what warnings must be in medical device IFUs?

[25] *Id.* at 117:13-118:2.
[26] *Id.* at 219:4-13.
[27] Hinoul Testimony, *Batiste v. McNabb*, No. DC-12-14350 (Tex. Dist. Ct. 95th Dist. March 26, 2014), portions attached as Exhibit F, at 55:1-13.

> A. I guess I believe I do know what they are. Again, it relates to, you know, specifically the safety of the -- of the device; that is important to me in IFUs. The potential complications that can be -- can be related to the device, specifically to the device. Does that answer your question?
>
> Q. Are those all the industry standards you're familiar with that govern what warnings must be in a medical device IFU?
>
> A. I'm sure that there are more.[28]

Dr. Ramsey's testimony speaks for itself. He has misconceptions about what information needs to be a part of the IFU, and he did not even realize they had been changed for two of the key products on which he is opining. This testimony reveals that he does not have the necessary knowledge to qualify as an expert witness.

C. Dr. Ramsey's testimony reveals that he is approaching the issue as a clinician, not as a scientist who is trying to determine whether the products at issue are actually safe.

In addition to a lack of knowledge on key topics, Dr. Ramsey simply does not approach issues from a scientific perspective. Perhaps Dr. Ramsey's lack of qualification as an expert with specialized, scientific knowledge is best seen in the following exchange:

> Q. The discussions Ethicon medical directors had inside the company about the warnings in the TVT IFUs are not relevant to you, correct?
>
> A. … So once it is in the IFU -- and I've looked at the IFU and I think the IFU is adequate -- whatever went on within Ethicon doesn't pertain to me. I mean, that's all internal business decisions that don't apply to me clinically.[29]

That testimony reveals that Dr. Ramsey is viewing the questions presented to him as a clinician, not as a scientist. He is a urologist—one who specializes in treating males—who has implanted some TVT products in women, but he has not done an in-depth study of the devices at

[28] Ramsey Dep., Ex. B, at 112:9-113:7.
[29] *Id.* at 210:7-9, 14-19. It is somewhat revealing that Dr. Ramsey refers to the decisions as to which warnings to put into the IFU as "business decisions." But ultimately, that aspect of his statement is not important to the question of his qualifications.

issue. Dr. Ramsey may be qualified to implant a TVT device. But he is not qualified to give opinions about Ethicon's devices, under *Daubert*, if he has not concerned himself with how Ethicon—and others—view the safety of the device. The only basis for his opinions seems to be that he has used the TVT devices and likes how they perform.

This Court has been clear that clinical experience, without more, does not qualify someone as an expert, whether the topic is the properties of the mesh, the safety of the mesh, or the adequacy of the warnings in the IFU. *See, e.g.*, *Mathison v. Boston Sci. Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *11 (S.D. W. Va. May 6, 2015) (expert's clinical experience alone was insufficient to qualify expert on design issues); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (expert's clinical experience alone was insufficient to qualify him on warnings issues).

Dr. Ramsey may be a good surgeon, but he is simply not qualified to give the opinions listed in his reports, including but not limited to opinions regarding the safety and efficacy of the TVT products, and opinions regarding the sufficiency of the IFU. All Dr. Ramsey has to rely on is his limited clinical experience and his literature review—which is suspect, as described below. These factors do not qualify him as an expert. *Cf. Wehling v. Sandoz Pharm. Corp.*, 162 F.3d 1158 (Table), 1998 WL 546097, at *4 (4th Cir. Aug. 20, 1998) ("Without prior training, education, or experience in the field, McBay's review of the literature, after he was retained as an expert witness in this suit, was insufficient to qualify him as an expert on the issues in dispute.").

II. Dr. Ramsey also did not engage in a reliable methodology, as evidenced by the fact that Ethicon steered him to the literature in his report, and by the fact that he ignored important information about the TVT products.

The two major reasons that Dr. Ramsey should be excluded from testifying are closely related. He lacks qualifications, and his methodology in reaching his opinions—to the extent

that he had one—was not reliable. He is not qualified, in part, because he does not have the knowledge necessary to be an expert, as described above. And, he does not have that knowledge because he did not do an exhaustive scientific investigation into the products on which he hopes to opine.

For instance, his alarming lack of knowledge regarding changes to the IFU speaks to his lack of qualifications, in that "knowledge" is one of the Rule 702 qualification points. But it also speaks to the failure of Dr. Ramsey's methodology. Anyone hoping to opine about the sufficiency of the TVT IFU, as Dr. Ramsey intends to do,[30] clearly should understand the content of the IFU and how that content has changed over the years. Yet, Dr. Ramsey did not know that the IFU for TVT and TVT-O had ever changed,[31] even though those IFU have been through multiple updates.[32] He was also unsure whether the IFU for TVT-Secur had ever changed[33] (the IFU did not change before the product was discontinued[34]).

Thus, the arguments above as to Dr. Ramsey's qualifications also help to demonstrate why his methodology in reaching his opinions was unreliable. Several other aspects of his testimony further show that Dr. Ramsey did not go through a true scientific process.

A. Dr. Ramsey's limited literature review consisted almost entirely of skimming articles that were chosen for him by Ethicon.

Dr. Ramsey's report cites to various studies, so presumably he will argue that his clinical experience and literature review support the reliability of his methodology. The problem is, Dr.

[30] Ramsey TVT Report, attached as Exhibit G, at 16.
[31] Ramsey Dep., Ex. B, at 121:20-122:9.
[32] Ethicon Labeling History, Ex. D.
[33] Ramsey Dep., Ex. B, at 211:4-5.
[34] Ethicon Labeling History, Ex. D.

Ramsey did not manage the literature review. In fact, his office only subscribes to two journals that discuss issues related to transvaginal mesh or the treatment of SUI.[35]

Ethicon clearly managed Dr. Ramsey's literature review. While Dr. Ramsey stated that he asked for some articles himself, he could not name one.

Q. Okay. And did you draft this reliance list?

A. I assisted with the drafting of this list.

Q. Okay. How did you assist in drafting this list?

A. The -- the Ethicon lawyers helped me with -- with some -- some of this.

***

Q. How long did you spend reviewing the materials listed in your reliance list?

A. Oh, gosh. I continue to do it, continue to review them. But probably 30 or 40 hours.

Q. You're continuing to review those materials, correct?

A. Yes.

Q. So, as of today, you have not reviewed every single one of the materials listed in your reliance list, correct?

A. I have reviewed all of them. I may not have read every single word in every one of them, but I've reviewed them and looked at them.

***

Q. The materials on your reliance list, did Ethicon provide you with these materials?

A. They helped with -- with this. There are some that are known fairly well, but – but, yes, I did have help.

Q. Okay. How did you get the internal documents?

A. Oh, Ethicon gave me the internal documents.

[35] Ramsey Dep., Ex. B, at 100:4-8.

Q. How did you get the medical literature?

…

A. By reading the journals, by going to conferences.

Q. Okay. Turn to page -- so you actually went and retrieved these articles listed in the medical --

A. So -- most of these were given to me, but I --

Q. Most of these were given to you by Ethicon?

A. -- but I knew what they -- I knew what a lot of them are.

***

Q. Ethicon physically gave you these documents?

A. Yes.

Q. And they're the ones who decided which articles to give you, correct?

A. Not all of them, no.

Q. Sometimes you asked for some articles?

A. Yes.

Q. Which ones?

A. Gosh, I can't --

Q. As you sit here today, you can't name a single article?

A. I can't -- I can't name a single article that I asked for specifically.[36]

Spending 30 or 40 hours reading parts of journal articles that are largely supplied by the defendant manufacturer is not a scientific process. This issue is particularly important for Dr. Ramsey, who does not have additional resume items to recommend him as an expert. As discussed above, he has not published papers on SUI, or conducted testing, or spoken to

[36] 45:24-47:4; 55:8-57:5.

conferences of urogynecologists. He is a urologist operates primarily on men. It is debatable whether a strong literature review could compensate for those short-comings, but it is clear that **this** one-sided literature review fails to do so. Consequently, Dr. Ramsey should be excluded. *See Mathison*, 2015 WL 2124991, at *6 ("An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead selectively [chooses] his support from the scientific landscape." (quotations omitted)).

B. Dr. Ramsey's failure to engage in a scientific methodology is revealed by his lack of knowledge regarding concerns expressed about the TVT-Secur from various sources, including Ethicon, the FDA, and the scientific literature.

Dr. Ramsey's lack of a reliable methodology is also seen in his lack of knowledge regarding important topics relating to pelvic mesh products. As this Court has repeatedly recognized, it is important for experts on either side to consider the opposing viewpoint with regard to the safety of mesh products—or the lack thereof. *See, e.g.*, *Mathison*, 2015 WL 2124991, at *7 (allowing Dr. Margolis's testimony because he sufficiently discussed opposing views and explained why he disagreed with them). Here, Dr. Ramsey demonstrated limited knowledge of safety concerns about TVT products expressed by Ethicon, by the FDA, and in the scientific literature. His answers reveal that he failed to do significant scientific research, and therefore his opinions should be excluded under *Daubert* as unreliable.

Though TVT-Secur has been removed from the market, it is Dr. Ramsey's product of choice. He testified that TVT-Secur is safer than TVT-Retropubic or TVT-O, and that mini-slings are safer than retropubic or obturator slings.[37] Yet, it is unclear what the source of this opinion is. What **is** clear is that Dr. Ramsey has not studied the problems with the TVT-Secur, such that he could offer an informed opinion about its safety. Remarkably, he denied that the FDA has ever raised any concerns about TVT-Secur.

[37] Ramsey Dep., Ex. B, at 140:11-25.

Q. Do you agree that the FDA's current position is that the safety of the TVT-Secur devices has not been adequately demonstrated?

A. I don't think that's their position.[38]

In reality, the FDA issued a "522 Order" stating that "FDA is concerned with potential safety risks as evidenced by adverse events reported to the FDA."[39] The FDA also order post-market surveillance of the TVT-Secur, to study the rates of organ perforation, bleeding, mesh exposure, mesh erosion, pelvic pain, infection, de novo dyspareunia, urinary retention, recurrent incontinence, other urinary problems, neuro-muscular problems, and revisions/surgeries.[40] The 522 Order leaves little doubt that the FDA was, in fact, concerned that the safety of TVT-Secur had not been demonstrated. Dr. Ramsey's failure to understand that very basic point demonstrates that he did not research the issue with any depth.

Dr. Ramsey also was not aware that Ethicon had referred to TVT-Secur as a failed product.[41] Apparently, the internal documents that Ethicon hand-picked for Dr. Ramsey did not include a memo from Ethicon's Dan Smith stating: "EWH&U could have had an improved TVT SECUR obturator only version in 2008 to address bleeding and consistent placement, but **TVT SECUR was considered a failure** and did not warrant line extensions."[42]

In addition, Dr. Ramsey stated he had not seen any literature expressing that the stiffness of the TVT-Secur could cause complications,[43] and he was not familiar with the research of Dr. Neuman.[44] In a 2011 article, Dr. Neumann noted the 7.9% dyspareunia rate for the TVT-Secur and wrote that this relatively high rate "might be explained in part by the rigidity and reduced

[38] *Id.* at 195:13-19 (objection omitted).
[39] FDA 522 Order, Jan. 3, 2012, attached as Exhibit H, at p. 1.
[40] *Id.* at p. 2, ¶ 1.
[41] Ramsey Dep., Ex. B, at 321:8-12.
[42] Smith Memo to several recipients, March 19, 2010, attached as Exhibit I, at ETH.MESH.06927249.
[43] Smith Dep., Ex. B, at 103:8-14.
[44] *Id.* at 366:15-24.

flexibility of the synthetic polypropylene implant because it is laser cut, which tends to result in a stiff tape edge."[45] One would think that an "expert" opining on the safety of TVT-Secur would address that study; but Dr. Ramsey had not even heard of Dr. Neuman.[46] Similarly, Dr. Ramsey was unfamiliar with a journal article written by a Gynecare consultant named Francis Habb. The article was titled: "TVT Secur Single-Incision Sling After 5 Years of Follow-Up: The Promises Made and the Promises Broken."[47] The article concluded that "the TVT SECUR definitely did not stand the test of time, with a 31% success rate after 4.5-yr of follow up … ."[48] Not only did Dr. Ramsey fail to explain away the contrary literature, he had not even heard of several key articles about the TVT-Secur—the safest of the TVT devices, in his mind.

This testimony further underscores that Dr. Ramsey's opinions are based mostly, if not entirely, on his clinical experience. Dr. Ramsey even discounted information that he saw in the scientific literature about dyspareunia because he had not seen it in his own practice.

> Q. Okay. The mesh used in the TVT line of products in your opinion cannot be a cause of dyspareunia, correct?
>
> A. I don't think that the mesh is a cause of dyspareunia.
>
> Q. Never, correct?
>
> A. I've never seen it.
>
> Q. Ever?
>
> A. I have not, not in my clinical practice.
>
> Q. You've never read about it either, have you?

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[45] Neuman, et al., *Transobturator vs Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-Year Follow-up*, J. OF MINIMALLY INVASIVE GYNECOLOGY, Nov.-Dec. 2011, article attached as Exhibit J, at p. 772.
[46] Ramsey Dep., Ex. B, at 366:22-24.
[47] *Id.* at 364:13-23.
[48] Haab, et al., *TVT Secur Single-Incision Sling After 5 Years of Follow-Up: The Promises Made and the Promises Broken*, EUROPEAN UROLOGY 62, 2012, article attached as Exhibit K, at 737.

> A. I've read about it in certain articles that suggest it, but I don't -- I don't think that's the case.[49]

Again, this testimony shows that Dr. Ramsey was not engaging in a scientific process. First, he was not aware of much of the key evidence against the safety and efficacy of TVT-Secur. And then, even if he did read about something in the scientific literature, he simply discounted that information if he had not seen the complication in his own practice—a practice in which he spends 70% of his time treating men.

That thought process is the antithesis of the scientific analysis that *Daubert* requires. Dr. Ramsey, therefore, should be precluded from testifying because his opinions are unreliable.

CONCLUSION

For all of the foregoing reasons, this Court should exclude Dr. Ramsey from testifying as an expert witness in the Ethicon Wave 1 cases. He is not qualified to serve as an expert on the safety and efficacy of the TVT products, or on the adequacy of the instructions for use. In addition, he did not engage in a reliable methodology. He scanned particular documents and articles hand-picked by Ethicon, and he demonstrated a complete lack of knowledge as to contrary statements by Ethicon employees, by the FDA, and within the scientific literature.

Dated: May 2, 2016

[49] Ramsey Dep., Ex. B, 264:11-265:1.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on May 2, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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